

## **REMARKS**

### **Status of the Claims**

Claims 1-12 are currently pending. Claims 13-16 have been withdrawn as they are directed towards non-elected subject matter. Claims 9 and 10 have been amended to be dependent from claim 8.

### **Support for the Claim Amendments**

Claims 9 and 10 have been amended to be dependent from claim 8. Claim 8 is directed towards a quadruplex "wherein the quadruplex is an intermolecular structure." Amended claim 9 is directed towards a species of the genus that is claimed in claim 8, namely, "wherein the quadruplex is an intermolecular parallel structure." Lastly, amended claim 10 is directed towards yet another species of the genus that is claimed in claim 8, specifically, "wherein the quadruplex is an intermolecular structure formed by a dimer of two intramolecular hairpin structures."

Support for these amendments can be found, for example, in the claims as originally filed and at paragraph 6 of International Publication Number WO 2004/036188.

Accordingly, no new matter has been added and the amendment can be properly entered.

### **The Group Restriction Requirement**

The Examiner is requiring restriction under 35 U.S.C. §121 and §372 to one of the following inventions:

- I. Claims 1-12, drawn to a method for identifying an antiviral candidate molecule;
- II. Claim 13, drawn to information characterizing the structure of an antiviral molecule; and

III. Claims 14-16, drawn to a method for inhibiting retroviral proliferation in a subject with an antiviral candidate molecule.

**The Group Election**

Applicants hereby elect Group I, drawn to, inter alia, a method for identifying an antiviral candidate molecule, including claims 1-12.

Applicant expressly reserves the right under 35 U.S.C. §121 to file a divisional application directed to the non-elected subject matter during the pendency of this application, or an application claiming priority from this application.

**The SubGroup-Species Restriction Requirement**

The Patent Office alleged that the pending claims of Group I comprise multiple patentably distinct species, or subgroups, at it was alleged that they lacked a single general inventive concept under PCT Rule 13.1.:

SubGroup I – retroviruses, e.g., as set forth in claim 2 (“... wherein the retrovirus is selected from the group consisting of human immunodeficiency virus (HIV), simian immunodeficiency virus (SIV), visna/maedi virus (VMV), caprine arthritis-encephalitis virus (CAEV), equine infectious anaemia virus (EIAV), feline immunodeficiency virus (FIV), bovine immunodeficiency virus (BIV), murine leukemia virus (MLV), human immunodeficiency virus (HIV), equine infectious anaemia virus (EIAV), mouse mammary tumor virus (MMTV), Rous sarcoma virus (RSV), Fujinami sarcoma virus (FuSV), Moloney murine leukemia virus (Mo-MLV), FBR murine osteosarcoma virus (FBR MSV), Moloney murine sarcoma virus (Mo-MSV), Abelson murine leukemia virus (A-MLV), avian myelocytomatosis virus-29 (MC29), and avian erythroblastosis virus (AEV)”); and

SubGroup II – different types of quadruplex structures as generically claimed in independent claim 1, and with exemplary species set forth in dependent claim 8 (“... wherein the quadruplex is an intermolecular structure”); dependent claim 9 (“...wherein the quadruplex is an intermolecular parallel structure”); and dependent claim 10 (“...wherein the

quadruplex is an intermolecular structure formed by a dimer of two intramolecular hairpin structures”).

### **The SubGroup-Species Election**

In response to the subgroup-species restriction requirement, Applicants elect the following species, all with traverse:

Subgroup (1) Regarding election and identification of an retrovirus, *e.g.*, as set forth in claim 2, Applicants elect a “human immunodeficiency virus (HIV)”, with traverse.

Subgroup (2) Regarding election and identification of different types of quadruplex structures, *e.g.*, as set forth in claims 8-10, Applicants elect the quadruplex structure described in claim 8 “wherein the quadruplex is an intermolecular structure”, with traverse.

Applicants respectfully submit that this election should be a species election (and not a subgroup/species election), and when the elected species are held to be allowable, Applicants are entitled to consideration (examination) of additional species; if all species are held to be allowable, a generic claim should be allowed (MPEP §809.02(a); pg 800-52 to 800-53, 8<sup>th</sup> Edition, rev. 3, August 2005).

### **Reasons to reconsider and withdraw restriction requirement**

Applicants respectfully request the Patent Office reconsider and, in part, withdraw the subgroup restriction requirement for the following reasons:

#### **All retroviruses and quadruplex structures should be rejoined to a generic Group I**

Applicants respectfully submit that all retroviruses, *e.g.*, as set forth in claim 2, and all quadruplex structures, *e.g.*, as set forth in claim 8, and amended claims 9 and 10, should be rejoined to a generic Group I. Amendments to claims 9 and 10 are discussed above.

Claim 2 is dependent on claim 1. Claims 9 and 10 are dependent on claim 8 which is dependent on claim 1. Claim 1 is directed towards a method for identifying an antiviral candidate molecule, which comprises

contacting a test molecule with a nucleic acid comprising a nucleotide sequence identical to or substantially identical to a nucleotide sequence in a central flap nucleic acid sequence of a retrovirus, wherein the nucleic acid comprises a quadruplex structure, and

detecting an interaction between the test molecule and the nucleic acid, whereby a test molecule that interacts with the nucleic acid is identified as an antiviral candidate molecule.

If the subgroup instant restriction requirement is allowed to stand, Applicants will not be allowed to claim their invention as they choose. If the invention is limited to all the subgroups set forth by the Office, the full scope of the genus claimed in claim 1 will never be examined. Even if Applicants filed divisional applications to all the subgroups (*i.e.*, all the retroviruses, *e.g.*, as set forth in claim 2, or the quadruplex structures of claims 8-10), the scope of the genus claimed in claim 1 will never be examined. In other words, if claim 1 is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not be the equivalent of the original claim.

The procedure for handling applications that include generic claims is set forth in 37 CFR §1.146. This rule provides that “[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.”

As stated in MPEP §809.02(a), “[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.” Thus, where generic claims are present, an applicant can be required to elect a species for initial

examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable (emphasis added). MPEP §809.02(a); pg 800-52 to 800-53, 8<sup>th</sup> Edition, rev. 3, August 2005.

In the instant restriction requirement, this required procedure is not being followed. Claim 1 is a proper generic claim within the requirements set forth in 37 CFR § 1.141. Claim 1 satisfies the definition of a generic claim as set forth in MPEP §806.04(d), in that it includes limitations that are not present in all claims that depend from it. Therefore, an election of species requirement is permissible, but a restriction requirement is not. (MPEP §806.04(d), pg 800-42 to 800-43, 8<sup>th</sup> Edition, rev. 3, August 2005).

Moreover, because this restriction requirement splits claim 1 into multiple groups (the subgroups the Office alleges are patentably distinct), the restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. 121, provides no legal authority for not examining a broad generic claim. See, In re Weber, 198 USPQ 328, 331 (CCPA 1978); In re Haas, 179 USPQ 623, 624-625 (In re Haas I) (CCPA 1973) and In re Haas 198 USPQ 334-337 (In re Haas II) (CCPA 1978). As stated in In re Weber:

“The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it.” 198 USPQ 328 at 334.

In a case such as the instant case, where a claim is generic, a restriction requirement is tantamount to a rejection of the claim. The CCPA made this point very clear in In re Haas I:

“We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained.” 179 USPQ at 625.

If the instant restriction requirement is allowed to stand, Applicants will not be accorded “the basic right of the applicant to claim his invention as he chooses.” In re Weber, 198 USPQ at 331.

In In re Weber, the CCPA stated that “[a]s a general proposition, an applicant has a right to have *each* claim examined on the merits” (198 USPQ at 331, emphasis in original). The Court went on to state that:

“If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.” 198 USPQ at 331.

Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. MPEP §803.02, pg 800-4 to 800-5, 8<sup>th</sup> Edition, rev. 3, August 2005. Even if Applicants were to file multiple divisional applications in addition to the instant application to obtain coverage for each of the alleged subgroups, Applicants would not have the opportunity to have their broader generic claim examined, i.e., Applicants would not have the opportunity to have that which they regard as their invention examined. The claims of the divisional applications would be limited to the particular subgroups. One seeking to avoid infringement could simply choose an alternative that is not specifically claimed in any particular (divisional) application. In effect, the restriction requirement is reading into Applicants’ independent claims limitations that are not present in the claims as filed. Claim 1 as filed and pending, for example, would never be considered, and thus never allowed, under the current restriction requirement. Only the dependent claims which are set forth in the respective subgroups would be examined.

Finally, Applicants also respectfully submit that all the species within each subgroup share a common inventive concept and thus should be rejoined under PCT Rule 13.1. The common inventive concept being the use of a novel nucleic acid comprising a nucleotide sequence identical to or substantially identical to a nucleotide sequence in a central flap nucleic acid sequence of a

retrovirus, wherein the central flap nucleic acid comprises a quadruplex structure, to identify an antiviral candidate molecule. In addition, it should be noted that the quadruplex structure in claim 1 is generic to “(1) an intermolecular structure, (2) an intermolecular parallel structure, and (3) an intermolecular structure formed by a dimer of two intramolecular hairpin structures” as discussed on page 4, section B of the Office Action.

Applicants therefore respectfully request that the instant restriction requirement with respect to all the subgroups be withdrawn (and rejoined as a generic restriction Group I) and treated as though it were a species election under the procedure set forth in MPEP 809.02(a).

Pursuant to 37 C.F.R. § 1.144, Applicants reserve the right to petition for review of the restriction requirement at any time prior to appeal. Applicants also submit that because the instant restriction requirement is tantamount to a rejection of the generic claim 1, the restriction requirement is appealable to the Board of Patent Appeals and Interferences. In re Haas I. If the instant restriction requirement is allowed to stand, Applicants will not be accorded “the basic right of the applicant to claim his invention as he chooses.” In re Weber. It is improper for the Office to refuse to examine that which Applicants regard as their invention. MPEP §803.02, pg 800-4 to 800-5, 8<sup>th</sup> Edition, rev. 3, August 2005.

Accordingly, Applicants respectfully request reconsideration of the restriction requirement and request that the restriction requirement with respect to all the subgroups be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a).

### CONCLUSION

In this response, Applicants have elected the invention of Group I. Applicants traversed the subgroup restriction requirement and respectfully requested the restriction be withdrawn, in part, as discussed above.

Applicants set forth distinct and specific errors in the restriction requirement and reasons for the Patent Office to reconsider and withdraw, in part, the restriction requirement. Applicants have also requested that the restriction requirement with respect to all the subgroups be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a). Applicants have elected subgroups (species) with traverse, and respectfully request that when the elected species is held to be allowable, Applicants are entitled to consideration (examination) of additional species, and if all species are held to be allowable, a generic claim should be allowed.

Accordingly, Applicants have preserved their right to petition the restriction to the Group Director under 37 CFR §1.144; see also MPEP §818.03(c); pg 800-60, 8th Edition, rev. 3, Aug. 2005. Applicants will defer submission of the petition (which can be deferred until allowance of the claims).

It is believed that the all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing (532232000900). However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.



If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858 720 7961.

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Respectfully submitted,

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